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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,602	06/26/2001	Alexey B. Dyatkin	ORT-1451	2105

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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/891,602

Applicant(s)

Dyatkin, A.B. et al.

Examiner

CHARANJIT AULAKH

Art Unit

1625



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO-413) Paper No(s). 5
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-57, drawn to compounds of formula (I) where B2 represents C1 alkylene or C1 alkenylene and B1 represents C1-2 alkylene or C1-2 alkenylene, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 112.

II. Claims 1-23, 25-27 and 32-57, drawn to compounds of formula (I) where B1 and B2 are other than defined above for group I, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 450+.

2. The inventions I and II as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of invention II prima facie obvious. Search required for e.g ; compounds of invention I in class 546 is not the same search required for e.g ; compounds of invention II in class 540 and therefore, constitutes a burdensome search. Thus, restriction requirement as indicated above is proper.

3. During a telephone conversation with the applicant's attorney, Mr. Hal B. Woodrow on April 2, 2002, a provisional election was made with traverse to prosecute the invention of group I (

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compounds of claim 24 as species ), claims 1-57. Affirmation of this election must be made by applicant in replying to this Office action.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Independent claims 1, 24, 25 and 26, the terms “racemic mixtures, diastereomers and enantiomers thereof” are indefinite since it is not clear which racemate, diastereomer or enantiomer is being referred here and furthermore, the actual steps for preparing them are missing. The applicants are suggested to delete these terms to overcome this rejection.

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Claims 37-43 are essentially duplicate of claims 46-51. The language of claims 37-43 is confusing and therefore, the applicants are suggested to cancel claims 37-43. Also, all claims 41-43 depend upon claim 40 and there is substantial overlap of various disorders being treated in claims 41, 42 and 43.

Claim 45 is a substantial duplicate of claim 44. The applicants are suggested to cancel this claim since the language of claim 44 is proper.

In claim 47, it is not clear what the applicants mean by the term “ selective antagonist of an alpha4 integrin receptor and an antagonist of atleast two alpha4 integrin receptors “. The applicants are suggested to include the specific subtypes of alpha4 integrin receptors to clarify this confusion. Claims 50 and 51 both depend upon claim 46 and there is an overlap of certain disorders being treated such as inflammatory and autoimmune disorders.

Claims 52 and 53 depend upon claim 46 and refer to compound of claim 46. However, claim 46 is directed to a method for the treatment of ----. An appropriate correction is required.

Claims 55 and 56 depend upon claim 46. Claim 46 is directed to a method of treating diseases by administering therapeutically effective amount of compound of claim 1. However, claims 55 and 56 refer to administering pharmaceutically composition of claim 44 which means administering compound of claim 1 twice. An appropriate correction is required.

#### IMPROPER MARKUSH GROUP

7. Claims 1-23, 25-27 and 32-57 are objected as being directed to Improper Markush Group since the variables B1 and B2 are critical for the common core of the instant compounds. The

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applicants are suggested to amend the claims to read upon the elected group to overcome this objection.

*Allowable Subject Matter*

8. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds directed to the elected group are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Merck & Co. ( WO 98/53814 ) discloses heterocyclic amide compounds as cell adhesion inhibitors which are closely related to the instant compounds. However, the closely related compounds ( see compounds of claims 13-16 ) of Merck & Co. differ in structure from the instant compounds in having a different heterocyclic ring ( isoquinoline or pyrrole ring instead of an aza-bridged bicyclic ring ) and furthermore, there is no teaching or suggestion in the prior art to modify the compounds of Merck & Co. to prepare the instant compounds.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on " Monday-Thursday " from 7:30 A.M. to 6:00 P.M.

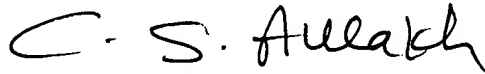
If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, reading "C. S. Aulakh". The signature is written in a cursive style with a large, sweeping "C" and "S".

CHARANJIT S. AULAKH

PRIMARY EXAMINER